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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,773	11/17/2003	Fatih M. Uckun	12152.0076USC2	8890

7590 09/25/2006

Attention of Anna Nelson
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EXAMINER	
TRUONG, TAMTHOM NGO	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary for Applications Under Accelerated Examination	Application No.	Applicant(s)	
	10/715,773	UCKUN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Since this application has been granted special status under the accelerated examination program,

NO extensions of time under 37 CFR 1.136(a) will be permitted and a SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE:

ONE MONTH OR THIRTY (30) DAYS, WHICHEVER IS LONGER,
FROM THE MAILING DATE OF THIS COMMUNICATION – if this is a non-final action or a *Quayle* action.
(Examiner: For **FINAL** actions, please use PTOL-326.)

The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application. Any reply must be filed electronically via EFS-Web so that the papers will be expeditiously processed and considered. If the reply is not filed electronically via EFS-Web, the final disposition of the application may occur later than twelve months from the filing of the application.

Status

1)☐ Responsive to communication(s) filed on _____.

2)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

3)☒ Claim(s) *1,13,17,18,20-26 and 30-43* is/are pending in the application.

3a) Of the above claim(s) _____ is/are withdrawn from consideration.

4)☐ Claim(s) _____ is/are allowed.

5)☐ Claim(s) _____ is/are rejected.

6)☐ Claim(s) _____ is/are objected to.

7)☒ Claim(s) *1,13,17,18,20-26 and 30-43* are subject to restriction and/or election requirement.

Application Papers

8)☐ The specification is objected to by the Examiner.

9)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

10)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

11)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *East Search*.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 13, 17 and 18 (in part), drawn to compounds of formula I wherein:

- X is HN, $R_{11}N$;
- Two adjacent groups of R_1-R_8 do not form a ring;
- R_9 and R_{10} are not methylenedioxy;

and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents.

II. Claims 1, 13, 17 and 18 (in part), drawn to compounds of formula I wherein:

- X is S;
- Two adjacent groups of R_1-R_8 do not form a ring;
- R_9 and R_{10} are not methylenedioxy;

and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents.

III. Claims 1, 13, 17 and 18 (in part), drawn to compounds of formula I wherein:

- X is O;
- Two adjacent groups of R_1-R_8 do not form a ring;
- R_9 and R_{10} are not methylenedioxy;

and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents.

IV. Claims 1, 13, 17 and 18 (in part), drawn to compounds of formula I wherein:

- X is CH_2 or $R_{11}CH$;
- Two adjacent groups of R_1-R_8 do not form a ring;
- R_9 and R_{10} are not methylenedioxy;

and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents.

V. Claims 1, 13, 17 and 18 (in part), drawn to remaining compounds of formula I that are not mentioned in the above groups, and pharmaceutical composition thereof, classified in classes 514 and 544, various subclasses depending on substituents. Further restriction and/or election of species will be required if this group is elected.

VI. Claims 20-26 and 30-43 (in part), drawn to various methods of treatment using a compound of formula I, classified in class 514, various subclasses depending on substituents. Further restriction and/or election of species will be required if this group is elected.

Inventions of Groups I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct from each other by the combination of variables X and R_1-R_{10}.

The inventions of Groups I-V share a common core of *quinazoline.* Said core does not sufficiently define the invention, and it is not a contribution to the art. It is the combination of X,

and R_1-R_{10} that gives compounds of each group their unique physical, chemical properties and biological activities. Depending on what they represent, the claimed formula would have different structure. Furthermore, when R_9 and R_{10} form methylenedioxy, formula I would have a tricyclic core. Clearly, the Markush group of formula I is improper.

Thus, a reference anticipated or rendered obvious compounds of one group would not do so to those of other groups. Therefore, a separate search is required for each group.

The invention of Group VI is drawn to a method of treating various diseases which requires additional search and examination beyond the scope of the claimed compound. A reference reading on the compounds would not necessarily read on the claimed method.

Therefore, the search and examination for all 6 groups would impose a serious burden on the examiner in charge of this invention. Note, a preliminary search in EAST yields a total of 10,671 hits which clearly shows an overwhelming number of references for consideration.

Due to the complexity nature of the grouping, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims **will be fully examined for patentability in accordance with 37 CFR 1.104**. Thus, to be allowable, **the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.** Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim

will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tamthom N. Truong
Examiner
Art Unit 1624

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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9-18-06